

**DOCKET NO.:** JANS-0031 (JAB-1531 US)

**PATENT**

**Application No.:** 10/088,805

**Office Action Dated:** February 9, 2004

**REMARKS/ARGUMENTS**

Claims 1 to 10, 12 to 22, and 24 to 29 are pending in this application. Applicants are herein amending claim 1 and cancelling claims 14 to 27, and 29 without prejudice or disclaimer. Claims 1 to 10, 12, 13, 28, and 29 are rejected under 35 U.S.C. §§ 112 (second paragraph) and 103(a). After entry of the amendment, claims 1 to 10, 12, 13, and 28 will be pending in the application.

**Amendments**

Applicants are herein amending claim 1 to explicitly define the term “Het” (line 18) as “an aliphatic or aromatic heterocyclic radical, wherein said aliphatic heterocyclic radical is optionally substituted with an oxo group and wherein said aromatic heterocyclic radical is optionally substituted with hydroxy.” Support for the amendment may be found in the specification on, *inter alia*, page 3, lines 31 to 37 and original claim 1.

Applicants are herein canceling claims 14 to 27, and 29 without prejudice or disclaimer. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter.

Applicants respectfully submit that the amendments to the claims do not introduce any new matter and are fully supported by the specification and claims, as originally filed.

**Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1 to 10, 12, 13, 28, and 29 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite, specifically with respect to the term “Het” in claim 1, line 18. Applicants traverse the rejection because the term is explicitly defined on page 3, lines 31 to 37 and claims 1 to 10, 12, 13, 28, and 29 are therefore definite. Nonetheless, in an

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effort to expedite prosecution, applicants are amending claim 1 to explicitly include the definition of the term “Het” in claim 1, thereby rendering the rejection of claims 1 to 10, 12, 13, 28, and 29.

Accordingly, applicants request withdrawal of the rejection of claims 1 to 10, 12, 13, 28, and 29, under 35 U.S.C. § 112, second paragraph.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1 to 10, 12, 13, 28, and 29 are rejected under 35 U.S.C. § 103(a), as allegedly obvious over US-B-6,197,779 (*Andries*) in view of US-5,939,099 (*Grabowski*). Applicants respectfully traverse the rejection. *Andries* only qualifies as prior art under 35 U.S.C. § 102(e) with respect to the subject application. Both *Andries* patent and the subject application were commonly owned by Johnson & Johnson at the time the subject invention was made. Accordingly, *Andries* is not available as prior art in accordance with 35 U.S.C. § 103(c).

Furthermore, applicants respectfully submit that, even if *Andries* were available as prior art, the combination of the *Andries* reference with the secondary reference, *Grabowski*, teaches away from solid dispersions of antiviral agents with water-soluble polymers because *Grabowski*’s compositions always contain at least 10%, preferably 20%, by weight, of a water-insoluble polymers, even where rapid release is desired (See, for example, column 3, lines 52 to 54). Applicants claimed solid dispersions, on the other hand, are designed for immediate release upon oral ingestion when the particles are contacted with a liquid medium, such as gastric juices (page 34, lines 28 to 30). Furthermore, the solid dispersions of the claimed invention have good bioavailability because the claimed particles disintegrate rapidly in the stomach and are liberated such that they are kept away from one another so that they do not coalesce, giving undesirable local high concentrations of the antiviral compounds and increasing the chance that the drug precipitates. Accordingly, there is no disclosure,

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teaching, or suggestion in the combination of *Andries* and *Grabowski* to form the claimed solid dispersions of antiviral agents.

Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

**Information Disclosure Statements**

In a telephone discussion with the undersigned attorney on March 3, 2004, Examiner Webman noted that the statement in the Office Action indicating that the references cited on the Form PTO-1449 that accompanied the Information Disclosure Statements mailed June 21, 2002 and July 12, 2002 were not of record was inaccurate.

**Conclusions**

Applicants respectfully request:

- (1) acknowledgement of the art cited in the Information Disclosure Statements mailed June 21, 2002 and July 12, 2002;
- (2) entry of the amendment to the claims;
- (3) reconsideration and withdrawal of the rejection of the claims; and
- (4) allowance of claims 1 to 10, 12, 13, and 28, as amended.

If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (215) 557-3861.

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